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| APPLICATION NO.           | FILING DATE           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-----------------------|----------------------|---------------------|------------------|
| 10/533,300                | 10/24/2005            | Wolfgang Meder       | 37998-237420        | 2359             |
| 26694<br>VENABLE LL       | 7590 06/12/2007<br>.P |                      | EXAMINER            |                  |
| P.O. BOX 34385            |                       |                      | KEMMERER, ELIZABETH |                  |
| WASHINGTON, DC 20043-9998 |                       |                      | ART UNIT            | PAPER NUMBER     |
|                           |                       |                      | 1646                |                  |
|                           |                       |                      |                     | ·                |
|                           | •                     |                      | MAIL DATE           | DELIVERY MODE    |
|                           |                       |                      | 06/12/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |   | A 11 (1 1)  |  |  |  |  |
|--|---|---|--|--|--|--|
| Office Action Summary  |   | Application No.   | Applicant(s)   |  |  |  |
|  |   | 10/533,300 `  | MEDER ET AL.   |  |  |  |
|  |   | Examiner  | Art Unit   |  |  |  |
|  |   | Elizabeth C. Kemmerer, Ph.D.  | 1646   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |   |  |  |  |  |
| Status   | •   |   |  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 29 Ap   | <u>oril 2005</u> .  |  |  |  |  |
| 2a) <u></u> □  | This action is <b>FINAL</b> . 2b) This action is non-final.   |   |  |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |   |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |  |  |  |  |
| Dispositi  | ion of Claims   |   | •  |  |  |  |
| 5)<br>6)<br>7)   | Claim(s) 11-26 is/are pending in the application 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) 11-26 are subject to restriction and/or                              | yn from consideration.  |  |  |  |  |
| Application Papers   |   |   |  |  |  |  |
| 10)  | The specification is objected to by the Examiner The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Examiner | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a).<br>sected to. See 37 CFR 1.121(d). |  |  |  |
| Priority u   | under 35 U.S.C. § 119   |   |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |   |  |  |  |  |
| 2) Notice 3) Information   | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) tr No(s)/Mail Date   | 4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6) Other:                                | ate  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11-13, 16-18, and 25, drawn to COM (TIG2) polypeptides, derivatives thereof, and pharmaceutical compositions comprising said polypeptides.

Group II, claim(s) 14, drawn to a method of screening a library.

Group III, claim(s) 15, drawn to a method of preparing COM (TIG2) polypeptide.

Group IV, claim(s) 19 and 20, drawn to methods of treating disease comprising administering COM (TIG2) polypeptide.

Group V, claim(s) 21-24, drawn to methods of diagnosing disease using COM (TIG2) polypeptide.

Group VI, claim(s) 26, drawn to an immunoassay kit comprising COM (TIG2) antibodies.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The PCT rules define a special technical feature as that feature that makes a contribution over the prior art. However, the polypeptide defined by claim 11 (the first claim in this application) does not make a contribution over the art. Specifically, Nagpal et al. (1997, J. Invest. Dermatol. 109:91-95) discloses a COM (TIG2) polypeptide "having" or comprising the amino acid sequence shown in claim 11 (SEQ ID NO: 1). See Figure 2 on page 93. Therefore, since claim 11 does not define subject matter that makes a contribution over the prior art, the first claimed invention lacks a special technical feature. It follows that the other claimed inventions cannot share a special technical feature with the first claimed invention.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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## Rejoinder

The examiner has required restriction between product (Group I) and process (Groups II-V) claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ECK** 

ELIZABETH C. KEMMERER. PH.D. PRIMARY EXAMINER

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